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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/309,689	05/11/1999	NORMAN ORENTREICH	4555-45	7858

570 7590 03/23/2005

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EXAMINER	
MOHAMED, ABDEL A	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 03/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/309,689	ORENTREICH ET AL.	
	Examiner	Art Unit	
	Abdel A. Mohamed	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

ACKNOWLEDGMENT OF REMARKS AND STATUS OF THE CLAIMS

1. The remarks filed 12/6/04 is acknowledged, entered and considered. Claims 23-42 are now pending in the application. The rejection under 35 U.S.C. 103(a) over the prior art of record is withdrawn in view of the following new grounds of rejections.

CLAIMS REJECTION-35 U.S.C. § 102(b)

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) The invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 23, 24, 26-28 and 30-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Reckel (U.S. Patent No. 4,046,871).

The reference of Reckel ('871 patent) discloses an injectable material comprising cross-linked blood plasma protein (albumin), wherein the cross-linkages comprise at least one intermolecular amide bond, and wherein the cross-linkages are zero-length cross linkages (See e.g., col. 2, lines 20-60 and col. 5, lines 1-5) as directed to claims

23 and 24. On col. 3, lines 5 to 30, the '871 patent states that the total albumin (plasma protein) content of the composition suitable for diagnostic purposes (injectable material) is from about 10% to about 35% by weight, which overlaps with the limitations of about 1% to about 10% and the composition further comprises a physiologically acceptable fluid which is in amount of 90% because if the total albumin content is about 10%, the rest 90% is physiological fluid, and as such meets the limitations of claims 26-28.

With respect to the preparation of an injectable material, the reference teaches on col. 4, lines 60 to col. 6, lines 64 the preparation of polymers by contacting serum albumin with a peptide bond forming reagent whereupon a reaction takes place between an albumin molecule and the reagent with the formation of an intermediate followed by the reaction of the intermediate with another molecule of albumin to form a dimmer of albumin which thereafter undergoes further similar reaction to from successively, a trimer, tetramer and higher polymer of albumin, wherein the initial reactions to from the dimmer (n in Formula I is 0). Thus, showing the formation of cross-linkages using a zero-length cross-linking agents such as isoxazolium, carbodiimides, 1-ethyl-3-(3-dimethyl-aminopropyl)-carbodiimide, and the like, and as such meets the limitations of claims 30, 31 and 35-37. On col. 7, lines 36-43, the reference states that for carrying out the polymerization step, the molar ratio of the peptide bond forming reagent to albumin may vary from 1:1 to about 60:1 depending in part on whether the reagent is isoxazolium or a carbodiimide. Thus, overlapping with the limitation of claim 38, which mixes the zero length cross-linking agents with the protein portion in an amount of at least about 0.1% by volume of the protein portion.

Further, on col. 8, lines 54 to col. 9. lines 13, the '871 patent states that the serological albumin compositions of the present invention suitable as diagnostic agents may be prepared by precipitating the albumins, separating them from the reaction mixture and dissolving in a physiological solution. The operation is generally carried out by first adjusting the pH of the polymerized albumin reaction mixture to within the range of from about 4.5 to about 7.0 with mineral acid, and then adding alcohol whereupon the desired polymerized albumin product comprising a mixture of polymers together with some unpolymerized albumin precipitates. Suitable alcohols for carrying out the precipitation include methanol, ethanol, isopropanol and other water-miscible alcohols, and the precipitate is separated and recovered from the reaction mixture by conventional procedures since the injectable material is useful for as diagnostic agent for antibody detection, naturally the diagnostic agent should be purified, sterilized and/or autoclaved for the compositions (injectable material) to be useful as diluents for reagent preparation and for titration media, and as antibody detecting media, and as meets the limitations of claims 32-34, 39 and 40. Therefore, in the absence of evidence to the contrary, the claimed injectable material and method of preparation thereof disclosed by the reference anticipates claims 23, 24, 26-28 and 30-40 as drafted.

Claims 25 and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Bini (U.S. Patent No. 6,020,181).

3. The reference of Bini ('181 patent) discloses compositions (injectable materials) containing a fibrinolytic matrix metalloproteinase for the performance of fibrinolytic or thrombolytic procedures, wherein the compositions show the cleavage of amide bond of K-E and E-K (i.e., lysine-glutamate amide bond). See e.g., Figure 7 as directed to claim 25. The compositions further comprise growth factor and enzyme inhibitors (See e.g., col. 4, lines 5-12 and col. 6, line 24), as such meets the limitation of claim 29. Thus, absence of evidence to the contrary, the injectable materials (compositions) disclosed by the reference anticipates claims 25 and 29 as drafted.

CLAIM REJECTIONS-35 U.S.C. § 112 2nd PARAGRAPH

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 41 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 41 is indefinite and confusing in the recitation "injecting a material into an intradermal compartment of the skin" because it is not understood what is meant by intradermal compartment. Also, it is not clear if the material is injected intradermally into the skin. Appropriate clarification is required.

CONCLUSION AND FUTURE CORRESPONDENCE

5. No claim is allowed.

Claims 41 and 42 are free of prior art because there is no motivation to inject intradermally cross-linked plasma proteins, wherein the cross-linkages comprise at least one intermolecular amide bond.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272 0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (571) 272 0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mohamed/AAM

March 15, 2005

JON WEBER
SUPERVISORY PATENT EXAMINER